CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 19-766/S040

PHARMACOLOGY REVIEW(S)

NDA 19-766/S-040 Review Completed: October 28, 1999

Sponsor: Merck & Co., Inc.; P.O. Box 4; West Point, PA 19486

PHARMACOLOGY REVIEW OF NDA SUPPLEMENT
Supplement to NDA 19-766 S #040 (June 30, 1999)

DRUG: Zocor™, Simvastatin

CATEGORY: HMG CoA Reductase Inhibitor, "statin"

Supplement #034 for NDA 19-766 (Zocor™, (simvastatin)) provides for the addition of a new dosage regimen. Additional changes to the clinical sections of the label were made. There were no pharmacology/toxicology studies submitted to this supplement and none were required. There were no changes made to the preclinical sections of the label. There is no need for further action from pharmacology.

/S/
Ronald W. Steigerwalt, Ph.D.
Pharmacology Team Leader
10/28/99

cc: NDA Arch
HFD510
HFD510/Steigerwalt/Simoneau
Recommendation code: AP

APPEARS THIS WAY
ON ORIGINAL

Comments: This efficacy supplement provides data to support revisions to the Dosage and Adminstration section of the label to provide the option of a starting dose of 40 mg Zocor for patients who require a large reduction in LDL-C (more than 45%).

Other proposed changes to the Dosage and Administration section are indicated in the annotated label and are intended to improve conciseness and clarity of prescribing information and to remove outdated information.

A request for a categorical exclusion is provided.

APPEARS THIS WAY
ON ORIGINAL